

## REMARKS

Claims 1, 2, 4-8 and 10-20 are pending in the application. The subject matter of claims 1 and 7 has been combined into new claim 23, and claims 1 and 7 have been cancelled. In addition, claim 8 has been amended to recite that the distillation apparatus contains a thin film or wiped-film evaporator connected to a fractionating column, and this same language has been incorporated into new claim 23.

Support for the limitation added to claim 8 and incorporated into claim 23 may be found, for example, in paragraphs [0049] - [00051], which state that the distillation apparatus can be a wiped-film or thin film evaporator and that a fractionating column can be used as part of the distillation apparatus. In addition, Example 6 recites the use of a thin film evaporator connected to a rectification column to conduct the distillation. Accordingly, it is submitted that the added language to claims 8 and new claim 23 does not introduce new matter. Claims 2 and 4-6 have been amended to change dependencies to new claim 23, in view of the cancellation of claim 1.

In view of the foregoing amendments, as well as the Remarks set forth below, reconsideration of the Examiner's rejections is respectfully requested.

### **35 U.S.C. §103(a) Rejection Based on Ghisalberti in view of Saebo et al.**

Claims 1, 2 and 4-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ghisalberti (WO2001/18161) ("Ghisalberti") in view of Saebo et al. (U.S. 6,410,761) ("Saebo"). According to the Office Action, Ghisalberti discloses a process for the preparation of conjugated linoleic acid (CLA), and further discloses that

the CLA can be refined by conventional refining techniques, such as vacuum distillation, in order to obtain high grade CLA. According to the Office Action, it would have been obvious to use conventional refining techniques, such as vacuum distillation, to provide a purified CLA product, as disclosed by Ghisalberti. Saebo is cited as disclosing that low residence time distillation can be used to obtain purified CLA. Reconsideration of the Examiner's rejection in view of the following remarks is respectfully requested.

The present claims recite a process for producing a refined conjugated linoleic acid containing material which is enriched in desirable c9,t11, t10,c12 isomers of the conjugated linoleic acid esters. As now recited in the amended claims, the process requires introducing a first ester stream into a distillation apparatus wherein the distillation apparatus is a wiped-film or thin film evaporator connected to a fractionating column having a heater operating at a temperature of 240° C to 270° C. The first ester stream is distilled in the distillation apparatus to produce a second ester stream that is enriched in the desirable isomers and reduced in unconjugated linoleic acid esters compared to the first stream.

The use of such a distillation apparatus that combines a wiped-film evaporator and fractionating column is an important distinction over prior art distillation methods because such a distillation apparatus achieves a significant increase in the desired isomers obtained in the final product stream, as well as a significant increase in product yield. As explained in the Affidavit of Joseph C. Rongione dated March 13, 2009 (previously submitted), Example 1 of the present application illustrates a molecular distillation process that utilizes a wiped-film evaporator arrangement. This distillation

process is similar to that disclosed in the Saebo patent. Example 6 of the present application illustrates a distillation process that combines a wiped-film evaporator with a fractionating column. As detailed in the Rongione Affidavit, a comparison of the results of Example 6 to those of Example 1 shows an improvement in the amount of desired isomers obtained, as well as a significant improvement in product yield, when a fractionating column is used in combination with a wiped-film evaporation unit to distill the ester stream.

Turning to the references cited by the Examiner, Ghisalberti discloses a process for preparing CLA by reacting a linoleic acid-containing oil with an excess of glycerol and an alkali metal hydroxide at temperatures of 200° C to 250° C. (Ghisalberti at page 5 lines 4-8.) The resulting CLA from the alkaline isomerization of linoleic acid is a complex mixture of CLA isomers, including a full range of 11,13, 9,11 and 10,12 CLA isomers. (Ghisalberti at page 8, lines 4-13.) The most abundant isomers include the c9, c11 and c10, c12 isomers, id., neither of which are preferred isomers in accordance with the present application. Ghisalberti discloses that the resulting CLA mixture can optionally be refined to provide a purified, odorless and tasteless CLA using conventional techniques such as drying under a vacuum, clarification by bleaching earth, and stripping by vacuum distillation techniques. Such conventional techniques to remove minor impurities affecting odor and taste do not provide any suggestion of how to remove major components, such as unconjugated linoleic acid, and increase the amount of desirable isomers in the product ester stream. Nor do such conventional techniques suggest the presently claimed distillation step requiring use of a wiped-film

or thin film evaporator connected to a fractionating column having a heater operating at a temperature of 240° C to 270° C. Nowhere does Ghisalberti disclose or suggest how to enrich (increase) the amount of c9,t11 and t10,c12 isomers in the final product. Although the Office Action states that Ghisalberti provides an enriched product, such a statement is not supported by the Ghisalberti disclosure. Merely removing impurities that affect odor and taste does not result in a product enriched in particular desirable isomers. Moreover, since Ghisalberti discloses that his product CLA is a complex mixture of CLA isomers, and that such a complex mixture is desired (see Ghisalberti at page 8, lines 14-20), Ghisalberti does not disclose or suggest the desirability of, let alone how to obtain a resulting CLA ester stream that is enriched in c9,t11 and t10,c12 isomers, as required by the present claims.

The citation to Saebo does not satisfy the deficiencies noted in Ghisalberti. Saebo discloses distillation in a molecular distillation plant to purify CLA. (Saebo at Col. 10, lines 27-31.) Saebo emphasizes that the advantage of this system is the short time (less than one minute) at which the CLA is held at an elevated temperature. In view of this teaching it would not have been obvious to one of skill in the art to couple a wiped-film or thin film evaporator (which is a type of molecular distillation) with a fractionating column, as required by the present claims, since the addition of a fractionating column necessarily increases the time that the CLA ester stream is exposed to an elevated temperature. The residence time of the CLA ester stream in the fractionating column is on the order of 30 minutes, which is significantly greater than the less than one minute exposure to elevated temperatures disclosed by Saebo. Moreover, one would expect

from the Saebo disclosure that increasing the time that the CLA ester stream is exposed to elevated temperatures would lead to the formation of undesirable isomers. A comparison of the results from Example 1 of the present application (thin film evaporator only as the distillation apparatus) with the results from Example 6 (thin film evaporator connected to a fractionating or rectification column) shows that adding the fractionating column actually increased the amount of desired CLA esters, as well as increased the product yield. See, March 13, 2009 Rongione Affidavit at ¶10. This result is surprising and unexpected given Saebo's emphasis on short exposure time to elevated temperatures.

It is therefore submitted that the proposed combination of Ghisalberti and Saebo does not disclose or suggest the presently claimed distillation process wherein a CLA ester stream is distilled in a thin film or wiped-film evaporator connected to a fractionating column having a heater operated at a temperature in the range of 240° C to 270° C to obtain a CLA ester stream enriched in c9,t11, t10,c12 isomers.

**35 U.S.C. §103(a) Rejection Based on Saebo in view of Baltes et al., Sachtlar and Ghisalberti**

Claims 8 and 10-20 have been rejected as being unpatentable over Saebo in view of Baltes et al. (U.S. 3,162,658) ("Baltes"), in view of Sachtlar (U.S. 5,326,925) ("Sachtlar"), and further in view of Ghisalberti. According to the Office Action, Saebo discloses a process for producing CLA esters by an esterification process involving methanol, followed by an isomerization step. Baltes is cited for disclosing an alkali metal catalyst to catalyze the isomerization step, and Sachtlar is cited for allegedly

disclosing a dual reaction system in an isomerization process. Ghisalberti is cited as above, for allegedly disclosing distillation techniques. According to the Office Action, it would have been obvious to produce a CLA material as suggested by Saebo, and modify the isomerization step as suggested by Baltes, using a dual reaction zone apparatus for the isomerization, as suggested by Sachtler. The resulting CLA ester stream could then be purified using conventional vacuum distillation techniques, as suggested by Ghisalberti. To the extent that the Examiner's rejection is applied against the claims, as amended, it is respectfully traversed.

The presently amended claims are directed to a process that achieves a CLA ester stream that is enriched in desired c9,t11, t10,c12 isomers of CLA esters. The resulting enriched CLA ester stream is obtained by distilling a first CLA ester stream in a distillation apparatus that combines a wiped-film or thin film evaporator and a fractionating column having a heater operating at a temperature of 240° C to 270° C, to produce a second ester stream that is enriched in the desirable CLA isomers.

As pointed out above in connection with the rejection of claims 1, 2 and 4-7, neither Ghisalberti nor Saebo, alone or in combination, suggest the use of a thin film or wiped-film evaporator connected to a fractionating column to distill a CLA ester stream to increase the amount of desirable c9,t11 and t10,c12 CLA isomers, as now required by amended claim 8. In particular, Saebo discloses distilling a CLA product stream using molecular distillation and emphasizes the extremely short exposure time (less than one minute) to elevated temperatures that such a distillation system provides. Saebo provides no suggestion or motivation to one of skill in the art to couple the

molecular distillation system to a fractionating column, as specified in amended claim 8, since to do so would necessarily increase the exposure time to elevated temperatures, contrary to the teachings of Saebo.

Ghisalberti discloses that optional conventional refining techniques can be employed to further refine the CLA to provide a purified, odorless and tasteless CLA. The conventional refining techniques mentioned by Ghisalberti include drying under a vacuum, using bleaching clay and "stripping as vacuum distillation techniques." These techniques are all known techniques for removing trace impurities that effect the color, odor and taste of the product. Such techniques are not known techniques for removing major components from an ester stream to significantly change the composition of the ester stream. Thus, the mere mention by Ghisalberti of optional conventional refining techniques for removing trace impurities does not suggest to one of skill in the art how to distill major components from a CLA ester stream to provide a product ester stream that is enriched in desirable CLA isomers. Such a result is achieved by the presently claimed process wherein the CLA ester stream is distilled in a distillation apparatus that employs a thin film or wiped-film evaporator connected to a fractionating column having a heater operating at a temperature of 240° C to 270° C. Nothing in Ghisalberti discloses or suggests the use of such a system to obtain a product CLA ester stream enriched in c9,t11 and t10,c12 isomers.

The Examiner's citation of Baltes and Sachtler in combination with Saebo and Ghisalberti does not satisfy the deficiencies noted above with respect to Saebo and Ghisalberti. Baltes relates to a process for preparing conjugated linoleic acids and does

not mention or suggest any method of distilling conjugated linoleic acids. Sachtler is merely cited for disclosing a dual reaction system and does not relate at all to a process for preparing and distilling a conjugated linoleic acid ester stream. Neither Baltes nor Sachtler discloses or suggests distilling an ester stream containing CLA esters using a wiped-film or thin film evaporator connected to a fractionating column to obtain an ester stream enriched in c9,t11 and t10,c12 CLA isomers, as required by amended claim 8 and the claims dependent thereon. Therefore, even if the references were combined as proposed in the Office Action, the combination does not disclose or suggest the distillation step now recited in amended claim 8.

For all of the above reasons, it is submitted that the claims, as amended, are patentable over the art of record, and reconsideration of the application and allowance of the claims are respectfully requested.

The Commissioner is authorized to charge any necessary fees or credit any overpayment to Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

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Respectfully submitted,

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